UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARY HELEN YARBOROUGH, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ARDELYX, INC., MICHAEL RAAB, and JUSTIN RENZ, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Mary Helen Yarborough ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Ardelyx, Inc. ("Ardelyx" or the "Company"), analysts' reports and advisories about the Company, and other information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Ardelyx securities between October 31, 2023 and July 1, 2024, both dates inclusive (the "Class Period"), seeking to

recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officers.

2. Ardelyx is a biotechnology company focused on developing and commercializing therapies for, among other things, patients with chronic kidney disease ("CKD"). According to Ardelyx, 550,000 people in the U.S. suffer from end stage renal disease ("ESRD"), which is the final stage of CKD characterized by a progressive loss of kidney function.

3. Patients suffering from ESRD must undergo regular dialysis treatment—typically 3 times a week for 3-5 hours—in order to survive due to the critically important role the kidneys play in filtering waste from the bloodstream.

4. Over the last decade, Ardelyx has developed a novel active ingredient called tenapanor. On October 17, 2023, Ardelyx announced that tenapanor branded as XPHOZAH® was approved by the FDA to reduce elevated levels of phosphorus in the bloodstream in CKD patients on dialysis who either cannot tolerate or did not adequately respond to other therapies.

5. XPHOZAH is a single tablet taken twice daily that blocks phosphate absorption (*i.e.*, it is a phosphorus inhibitor). It can only be taken orally because its mechanism of action involves blocking uptake of phosphorus in the gastrointestinal tract. As such, there is no injectable version of XPHOZAH. This mechanism is relevant to how XPHOZAH is covered by Medicare.

6. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act ("MIPPA"), which, among other things, directed and authorized the Centers for Medicare and Medicaid Services ("CMS") (an agency within the U.S. Department of Health and Human Services) to create a bundled payment system for "renal dialysis services" known as the ESRD Prospective Payment System ("ESRD PPS bundle") under which a single bundled payment is

made under Medicare Part B to dialysis facilities to reimburse them for dialysis services, and dialysis-related drugs, laboratory tests, and other products and services that were previously billed separately.

7. When Congress created the ESRD PPS bundle payment system for "renal dialysis services," it limited the reach of the bundled payment to injectable drugs or biologicals, or their oral equivalent. In 2009, however, CMS proposed to include oral-only drugs with no injectable equivalent in the ESRD PPS bundle.

8. In 2012, Congress delayed the inclusion of oral-only drugs in the ESRD PPS bundle until January 1, 2016. Then in 2014, Congress further delayed such inclusion until January 1, 2025 ("Jan 2025 Deadline"). There is presently legislation pending—The Kidney PATIENT Act (H.R. 5074)—to further delay the inclusion until 2033.

9. In 2016, CMS introduced the ESRD PPS Transitional Drug Add-on Payment Adjustment ("TDAPA") program to pay for new ESRD-related therapies not yet in the ESRD-PPS bundle. TDAPA provides for an additional payment for two years for new ESRD-related therapies on top of the single bundled payment to enable CMS to gather sufficient claims data to incorporate the new therapy into the bundle and adjust the base payment rate. In 2024, CMS introduced a reduced add-on payment for an additional three years beyond the initial two years for therapies admitted into the TDAPA program.

10. Manufacturers must apply to include their therapies in TDAPA. *See* https://www.cms.gov/files/document/tdapa-application-requirements-updated-07112022.pdf.

11. With the Jan 2025 Deadline approaching, CMS began to take action to place oral-only drugs into the ESRP PPS bundle. On April 29, 2024, CMS issued guidance concerning inclusion of oral-only drugs in the ESRD PPS bundle effective January 1, 2025. Then on June 27,

2024, CMS released the proposed Calendar Year 2025 ESRD PPS rule in which it confirmed its intention to bring XPHOZAH and other oral-only ESRD-related drugs into the ESRD PPS bundle beginning January 1, 2025, and to cease separate payment for XPHOZAH and other such drugs under Medicare Part D on such date.

12. Shifting reimbursement for XPHOZAH into the ESRD PPS bundle—without applying to include XPHOZAH in TDAPA—will have a materially adverse effect on sales of XPHOZAH because if dialysis facilities are forced to pay for an oral-only drug like XPHOZAH using the single bundled payment that they receive from CMS, they will have less wherewithal and incentive to facilitate patients' access to XPHOZAH, and sales of XPHOZAH will suffer.

13. In its Forms 10-Q filed on October 31, 2023, and May 2, 2024, and in its Form 10-K filed on February 22, 2024, Ardelyx indicated that it would apply to include XPHOZAH in TDAPA. Further, on an earnings call on May 2, 2024, Defendant Michael Raab ("Raab") advised analysts that "our intent is to enter TDAPA." But then on July 2, 2024, Ardelyx shocked investors by disclosing that it had decided not to apply to include XPHOZAH in TDAPA.

14. Upon the above news, Ardelyx's stock price fell $2.29 per share, or 30.25%, to close at $5.28 per share on July 2, 2024.

15. Subsequently, on July 17, 2024, in partnership with the American Association of Kidney Patients and the National Minority Quality Forum, Ardelyx filed a lawsuit in the U.S. District Court for the District of Columbia against CMS claiming, among other things, that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS bundle is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations.

16. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

19. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Ardelyx is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

20. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

21. Plaintiff, as set forth in the attached Certification, acquired Ardelyx securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

22. Defendant Ardelyx is incorporated under the laws of the State of Delaware with principal executive offices located at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts

02451. During the Class Period, the Company's shares traded in an efficient market on the Nasdaq Global Market ("NASDAQ") under the ticker symbol "ARDX."

23. Defendant Raab served as Ardelyx's President, Chief Executive Officer ("CEO"), and a Director of the Company at all relevant times. During the Class Period, Defendant Raab sold 152,597 shares of Ardelyx common stock for total proceeds of over $1 million.

24. Defendant Justin Renz ("Renz") served as Ardelyx's Chief Financial & Operations Officer at all relevant times. During the Class Period, Defendant Renz sold 238,381 shares of Ardelyx common stock for total proceeds of over $1.5 million.

25. Defendants Raab and Renz are collectively referred to herein as the "Individual Defendants."

26. The Individual Defendants possessed the power and authority to control the contents of Ardelyx's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Ardelyx's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Ardelyx, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

27. Ardelyx and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Use of XPHOZAH to Treat Excessive Serum Phosphorus in Patients with Kidney Disease

28. Healthy kidneys remove excess phosphorus from the blood. But the kidneys of an individual suffering from CKD cannot adequately perform this function, leading to a condition known as hyperphosphatemia, or excessive serum phosphorus (*i.e.*, excessive phosphorus in the bloodstream). This condition can, among other effects, weaken bones by reducing their calcium content. Therefore, individuals with CKD must take phosphate binders to reduce the absorption of phosphorus into their bloodstream. Many CKD patients, however, cannot tolerate or do not adequately respond to phosphate binder therapy.

29. Ardelyx is a biotechnology company focused on developing and commercializing therapies for, among other things, patients with kidney disease. Over the last decade, Ardelyx has developed a novel active ingredient called tenapanor. Branded as XPHOZAH®, tenapanor was approved by the FDA on October 17, 2023, to reduce phosphorus in the bloodstream in CKD patients on dialysis who cannot tolerate or who do not adequately respond to phosphate binder therapy.

30. According to Ardelyx, eighty percent of patients with CKD on dialysis require therapeutic assistance to lower elevated levels of serum phosphorus, and phosphate binders are not sufficient for approximately 70% of such patients to achieve and maintain phosphorus levels within the target range.

31. XPHOZAH is a single tablet taken twice daily that blocks phosphate absorption (*i.e.*, it is a phosphorus inhibitor). It can only be taken orally because its mechanism of action involves blocking uptake of phosphorus in the gastrointestinal tract. As such, there is no injectable version of XPHOZAH. This mechanism is relevant to how XPHOZAH is covered by Medicare.

Medicare Coverage for XPHOZAH

32. According to Ardelyx, 550,000 people in the U.S. suffer from ESRD, which is the final stage of CKD characterized by progressive loss of kidney function.

33. Patients suffering from ESRD must undergo regular dialysis treatment—typically 3 times a week for 3-5 hours—in order to survive due to the critically important role the kidneys play in filtering waste from the bloodstream.

34. In 2008, Congress passed MIPAA, which, among other things, directed and authorized CMS to create the ESRD PPS bundle, a bundled payment system for "renal dialysis services" under which a single bundled payment is made under Medicare Part B to dialysis facilities to reimburse them for dialysis services, and dialysis-related drugs, laboratory tests, and other products and services that were previously billed separately.

35. When Congress created the ESRD PPS bundle payment system for "renal dialysis services," it limited the reach of the bundled payment to injectable drugs or biologicals "furnished to individuals for the treatment of end stage renal disease . . . and any oral equivalent form of such drug or biological." According to Ardelyx, this definition should exclude drugs like XPHOZAH—that are oral-only and have no injectable form—from the ESRD PPS bundle. Instead, according to Ardelyx, XPHOZAH should be covered under Medicare Part D, which reimburses pharmacies for sales of self-administered drugs prescribed for Medicare patients by their doctors.

36. Nevertheless, in 2009, CMS proposed to include oral drugs with no injectable equivalent in the ESRD PPS bundle. In 2012, however, Congress delayed the inclusion of oral-only drugs in the ESRD PPS bundle until January 1, 2016. Then in 2014, Congress further delayed such inclusion until the Jan 2025 Deadline. There is presently legislation pending—The Kidney PATIENT Act (H.R. 5074)—to further delay the inclusion until 2033.

TDAPA

37. TDAPA is a program that CMS introduced in 2016 to pay for new ESRD-related therapies not yet accounted for in the ESRD-PPS bundle. TDAPA provides for an additional payment for two years for new ESRD-related therapies on top of the single bundled payment to enable CMS to gather sufficient claims data to incorporate the new therapy into the bundle and adjust the base payment rate.

38. Since introducing TDAPA, CMS has refined the eligibility criteria and payment parameters. For example, when initially introduced, TDAPA was only available for new drugs outside of existing ESRD PPS functional categories. Such therapies would be paid at 106% of average sales price ("ASP") and be eligible for no less than 2 years of TDAPA while CMS collected drug cost and utilization data.

39. Beginning in 2024, CMS began making a post-TDAPA add-on payment for new renal dialysis drugs or biological products at 65% of expenditure levels in the prior year for an additional three years after the end of the initial two-year TDAPA period for those products. With this add-on payment, CMS provides 5 years of increased payment for certain new renal dialysis drugs and biological products (*i.e.*, the payment adjustment under TDAPA for 2 years, followed by a post-TDAPA payment adjustment for 3 years).

CMS Actions in Advance of the Jan 2025 Deadline

40. With the Jan 2025 Deadline approaching, CMS began to take action to place oral-only drugs into the ESRP PPS bundle. On April 29, 2024, CMS issued guidance concerning inclusion of oral-only drugs in the ESRD PPS bundle effective January 1, 2025. Then on June 27, 2024, CMS released the proposed Calendar Year 2025 ESRD PPS rule in which it confirmed its intention to bring XPHOZAH and other oral-only ESRD-related drugs into the ESRD PPS bundle

beginning January 1, 2025, and to cease separate payment for XPHOZAH and other such drugs under Medicare Part D on such date.

41. Shifting reimbursement for XPHOZAH into the ESRD PPS bundle—without applying to include XPHOZAH in TDAPA—will have a materially adverse effect on sales of XPHOZAH because if dialysis facilities are forced to pay for an oral-only drug like XPHOZAH using the single bundled payment that they receive from CMS, they will have less wherewithal and incentive to facilitate patients' access to XPHOZAH, and sales of XPHOZAH will suffer.

Materially False and Misleading Statements Issued During the Class Period

Materially False and Misleading Statements and Omissions in Ardelyx's Form 10-Q for Q3 2023

42. The Class Period begins on October 31, 2023, when Ardelyx filed a quarterly report on Form 10-Q with the SEC during pre-market hours, reporting the Company's financial and operating results for Q3 2023 ("Q3 2023 Form 10-Q"). The Q3 2023 Form 10-Q repeatedly stated that Ardelyx's future revenue and funding requirements, and the commercial success of XPHOZAH, would depend in part on:

> whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the end stage renal disease (ESRD) prospective payment system, and the manner in which such introduction into the ESRD prospective payment system may occur, ***including the length of any applicable Transitional Drug Add-on Payment Adjustment (TDAPA) period, the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period***[.]

(Emphasis added.)

43. The Q3 2023 Form 10-Q further stated:

> Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including XPHOZAH and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be

> available, as is the case today under Medicare Part D. ***ESRD facilities may nonetheless receive a TDAPA for new renal dialysis drugs and biological products that meet certain criteria for a period of two years***. The TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice. ***There can be no assurances that CMS will determine that XPHOZAH will qualify for TDAPA status. Even if deemed eligible by CMS, revenue for sales of XPHOZAH could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled into the ESRD PPS***. Moreover, in the post-TPDAPA [*sic*] period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that oral only phosphate lowering drugs will be reimbursed as part of the single bundled payment for Medicare patients. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for XPOHZAH at a price that is profitable for us. The inclusion of XPHOZAH in the ESRD PPS would affect our ability to optimize the commercialization of XPHOZAH and could materially impact our profitability, results of operations, financial condition, and prospects.

(Emphases added.)

44. Appended to the Q3 2023 Form 10-Q as exhibits were signed certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants attesting that (i) each had reviewed the Q3 2023 Form 10-Q, and (ii) to their knowledge, the Q3 2023 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

45. The statements referenced in ¶¶ 42-44 were materially false and misleading because the Q3 2023 Form 10-Q indicated that Ardelyx would apply to include XPHOZAH in TDAPA when, in fact, Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year 2025 ESRD PPS rule, which was only issued on June 27, 2024.

Materially False and Misleading Statements and Omissions in Ardelyx's Form 10-K for 2023

46. On February 22, 2024, Ardelyx filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for 2023 ("2023 Form 10-K"). The 2023 Form 10-K repeatedly stated that Ardelyx's future revenue and funding requirements, and the commercial success of XPHOZAH, would depend in part on:

> whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the end stage renal disease prospective payment system (ESRD PPS), and the manner in which such introduction into the ESRD PPS may occur, ***including the length of any applicable Transitional Drug Add-on Payment Adjustment (TDAPA) period, the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period***[.]

(Emphasis added.)

47. The 2023 Form 10-K further stated:

> Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including XPHOZAH and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ***ESRD facilities may nonetheless receive a TDAPA for new renal dialysis drugs and biological products that meet certain criteria for a period of two years.*** The TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice. ***There can be no assurances that CMS will determine that XPHOZAH will qualify for TDAPA status. Even if deemed eligible by CMS, revenue for sales of XPHOZAH could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled into the ESRD PPS***. Moreover, in the post-TPDAPA [*sic*] period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that oral only phosphate lowering drugs will be reimbursed as part of the single bundled payment for Medicare patients. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for XPOHZAH at a price that is profitable for us. The inclusion of XPHOZAH in the ESRD PPS would affect our ability to optimize the commercialization of XPHOZAH, will negatively and materially impact the

> revenue that we may generate on sales of XPHOZAH and could materially impact our profitability, results of operations, financial condition, and prospects.

(Emphases added.)

48. Appended to the 2023 Form 10-K as exhibits were signed certifications pursuant to Section 302 of the SOX by the Individual Defendants attesting that (i) each had reviewed the 2023 Form 10-K, and (ii) to their knowledge, the 2023 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

49. The statements referenced in ¶¶ 46-48 were materially false and misleading because the 2023 Form 10-K indicated that Ardelyx would apply to include XPHOZAH in TDAPA when, in fact, Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year 2025 ESRD PPS rule, which was only issued on June 27, 2024.

Materially False and Misleading Statements and Omissions in Ardelyx's Form 10-Q for Q1 2024

50. On May 2, 2024, Ardelyx filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for Q1 2024 ("Q1 2024 Form 10-Q"). The Q1 2024 Form 10-Q repeatedly stated that Ardelyx's future revenue and funding requirements, and the commercial success of XPHOZAH, would depend in part on:

> whether or when XPHOZAH, along with other oral End Stage Renal Disease-related drugs without an injectable or intravenous equivalent, are bundled into the end stage renal disease prospective payment system (ESRD PPS), and the manner in which such introduction into the ESRD PPS may occur, ***including the length of any applicable Transitional Drug Add-on Payment Adjustment (TDAPA) period, the amount of the add-on payment available during the TDAPA period and***

> ***whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period***[.]

(Emphasis added.)

51. The Q1 2024 Form 10-Q further stated:

> Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including XPHOZAH and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ***ESRD facilities may nonetheless receive a Transitional Drug Add on Payment Adjustment (TDAPA) for new renal dialysis drugs and biological products dispensed to Medicare beneficiaries that meet certain criteria for a period of two years***. The TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice. ***There can be no assurances that CMS will determine that XPHOZAH will qualify for TDAPA status, or that Medicare Advantage Plans will pay a TDAPA if XPHOZAH is dispensed to Medicare beneficiaries covered by Medicare Advantage Plans. Even if deemed eligible by CMS, revenue for sales of XPHOZAH could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled into the ESRD PPS***. Moreover, in the post-TPDAPA [*sic*] period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that oral only phosphate lowering drugs will be reimbursed as part of the single bundled payment for Medicare patients. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for XPOHZAH at a price that is profitable for us. The inclusion of XPHOZAH in the ESRD PPS would affect our ability to optimize the commercialization of XPHOZAH, will negatively and materially impact the revenue that we may generate on sales of XPHOZAH and could materially impact our profitability, results of operations, financial condition, and prospects.

(Emphases added.)

52. Appended to the Q1 2024 Form 10-Q as exhibits were signed certifications pursuant to Section 302 of the SOX by the Individual Defendants attesting that (i) each had reviewed the Q1 2024 Form 10-Q, and (ii) to their knowledge, the Q1 2024 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make

the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

53. The statements referenced in ¶¶ 50-52 were materially false and misleading because the Q1 2024 Form 10-Q indicated that Ardelyx would apply to include XPHOZAH in TDAPA when, in fact, Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year 2025 ESRD PPS rule, which was only issued on June 27, 2024.

Materially False and Misleading Statements and Omissions During Ardelyx's Q1 2024 Earnings Call

54. On May 2, 2024, Ardelyx held an earnings call ("Q1 2024 Earnings Call") to discuss its results for Q1 2024. During the call, an analyst posed a question concerning TDAPA:

> [I]f the bill is to be signed into law in the first half of '25, XPHOZAH would need to go into TDAPA. But then if the bill gets signed, XPHOZAH would need to come back out of TDAPA. Can you perhaps shed some light on that process and some of the logistics around that?

55. Defendant Raab responded:

> ***Currently, I think as we've said, our intent is to enter the TDAPA***. I think the specifics of what you're just describing, that's going to play out over time. ***But our current intent is to go through the process*** and as we hope and the work that we're doing and what Bunny Carter is doing and others on the Hill [ph], is understanding how important this medicine is for patients. This is a good policy.
>
> ***It's the right thing to do to ensure that patients get access to a drug that's already beginning to make a difference in many, many lives of dialysis patients***. So the work continues and the specifics about how things come in and out based upon these next 6 months or more, we'll get that to you as we also learn.

(Emphases added.)

56. The statements referenced in ¶ 55 were materially false and misleading because Defendant Raab indicated that Ardelyx would apply to include XPHOZAH in TDAPA when, in

fact, Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year 2025 ESRD PPS rule, which was only issued on June 27, 2024.

Regulation S-K Items 105 & 303

57. Throughout the Class Period, Ardelyx's periodic financial filings were required to disclose the adverse facts and circumstances detailed above under applicable SEC rules and regulations. Specifically, Item 105 of SEC Regulation S-K, 17 CFR § 229.105 ("Item 105"), required Ardelyx to "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the [Company] or offering speculative or risky" and "[c]oncisely explain how each risk affects the [Company] or the securities being offered." Defendants' failure to disclose that Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year 2025 ESRD PPS rule, violated Item 105 because this issue represented a material factor that made an investment in the Company speculative or risky.

58. For similar reasons, Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) ("Item 303"), which required Ardelyx to "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Defendants' failure to disclose that Ardelyx had not yet reached a firm decision concerning whether or not to apply to include XPHOZAH in TDAPA, and could not, in fact, decide whether or not to submit such an application to CMS until after Defendants first reviewed CMS's proposed Calendar Year

2025 ESRD PPS rule, violated Item 303 because this issue represented a known trend or uncertainty that was likely to have a material unfavorable impact on the Company's business and financial results. Specifically, shifting reimbursement for XPHOZAH into the ESRD PPS bundle—without applying to include XPHOZAH in TDAPA—was likely to have a materially adverse effect on sales of XPHOZAH because if dialysis facilities are forced to pay for an oral-only drug like XPHOZAH using the single bundled payment that they receive from CMS, they will have less wherewithal and incentive to facilitate patients' access to XPHOZAH, and sales of XPHOZAH will suffer.

The Truth Emerges

59. On July 2, 2024, during pre-market hours, Ardelyx issued a press release announcing that it had chosen not to apply to include XPHOZAH in TDAPA. Specifically, that press release stated, in relevant part:

> [I]n an effort to preserve patient access to its phosphate absorption inhibitor XPHOZAH® (tenapanor), the Company has chosen not to apply to include XPHOZAH in the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Transitional Drug Add-on Payment Adjustment (TDAPA).
>
> Ardelyx's analysis of the CMS policy to include oral-only medicines in the PPS and the Calendar Year 2025 ESRD PPS Proposed Rule released on June 27, 2024, revealed that the policy and the manner in which CMS intends to implement it are likely to cause significant restrictions on the use of XPHOZAH for all patients, irrespective of insurance coverage, because it interferes with the essential and appropriate shared decision-making between healthcare professionals and their patients.
>
> "At Ardelyx, we recognize that the only way innovative medicines like XPHOZAH can deliver their proven benefits to patients is by ensuring that those prescribed our medicines have access to them. XPHOZAH is the only therapy approved for patients who have an inadequate response to phosphate binder therapy and during the eight months it has been utilized in clinical practice, it is clear that patients are benefitting from and need continued access to this therapeutic option to reduce elevated serum phosphorus," said [Defendant] Raab, president and CEO of Ardelyx. "We have carefully and thoughtfully considered the potential impact of

> CMS's decision to add XPHOZAH into the Medicare PPS and have determined that even during the TDAPA period, the restrictions placed on XPHOZAH would be such that patient access to this novel therapy would be effectively eliminated for all patients. We believe that the proposed bipartisan legislation extending the exclusion of oral-only medications from the Medicare ESRD PPS is the best option to ensure continued patient access, and we call on Congress to pass the bill. Our decision not to apply for TDAPA reflects our steadfast commitment to preserving patients' access to our medicines and provides the best optionality for us to continue to explore alternatives to protect all patients."

60. This sudden change in strategy for XPHOZAH shocked the market, and upon the above news, Ardelyx's stock price fell $2.29 per share, or 30.25%, to close at $5.28 per share on July 2, 2024.

61. Subsequently, on July 17, 2024, in partnership with the American Association of Kidney Patients and the National Minority Quality Forum, Ardelyx filed a lawsuit in the U.S. District Court for the District of Columbia against CMS claiming, among other things, that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS bundle is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations.

62. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

SCIENTER ALLEGATIONS

63. During the Class Period, Defendants had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In particular, during the Class Period, Defendants intentionally or recklessly indicated that Ardelyx would apply to include XPHOZAH in TDAPA when, in fact, Defendants knew or recklessly disregarded that Ardelyx had not yet reached a firm decision concerning whether or not

to apply to include XPHOZAH in TDAPA, and could in fact decide not to submit such an application to CMS, which would materially affect sales of XPHOZAH.

64. Further, Defendants had both the motive and opportunity to commit fraud. Specifically, during the Class Period, while disseminating the materially false and misleading statements alleged herein to maintain artificially inflated prices for Ardelyx securities, the Individual Defendants enriched themselves by millions of dollars by engaging in insider sales of the Company's common stock while it traded at artificially high prices, with Defendant Raab selling 152,597 shares of Ardelyx common stock for total proceeds of over $1 million and Defendant Renz selling 238,381 shares of Ardelyx common stock for total proceeds of over $1.5 million.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

65. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Ardelyx securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

66. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Ardelyx securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may

be identified from records maintained by Ardelyx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

67. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

68. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

69. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Ardelyx;
- whether the Individual Defendants caused Ardelyx to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Ardelyx securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

70. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

71. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Ardelyx securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Ardelyx securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

72. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

73. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

74. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

75. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

76. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Ardelyx securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Ardelyx securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

77. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Ardelyx securities. Such reports, filings, releases and statements were

materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Ardelyx's finances and business prospects.

78. By virtue of their positions at Ardelyx, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

79. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Ardelyx, the Individual Defendants had knowledge of the details of Ardelyx's internal affairs.

80. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Ardelyx. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Ardelyx's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Ardelyx securities was artificially inflated throughout the Class Period. In

ignorance of the adverse facts concerning Ardelyx's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Ardelyx securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

81. During the Class Period, Ardelyx securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Ardelyx securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Ardelyx securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Ardelyx securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

82. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

83. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

84. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

85. During the Class Period, the Individual Defendants participated in the operation and management of Ardelyx, and conducted and participated, directly and indirectly, in the conduct of Ardelyx's business affairs.

86. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Ardelyx's financial condition and results of operations, and to correct promptly any public statements issued by Ardelyx which had become materially false or misleading.

87. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Ardelyx disseminated in the marketplace during the Class Period concerning Ardelyx's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Ardelyx to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Ardelyx within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Ardelyx securities.

88. Each of the Individual Defendants, therefore, acted as a controlling person of Ardelyx. By reason of their senior management positions and/or being directors of Ardelyx, each

of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Ardelyx to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Ardelyx and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

89. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Ardelyx.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: August 16, 2024

Respectfully submitted,

POMERANTZ LLP

/s/ Emily C. Finestone
Emily C. Finestone
Jeremy A. Lieberman
(*pro hac vice* application forthcoming)
J. Alexander Hood II
(*pro hac vice* application forthcoming)

600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (917) 463-1044
efinestone@pomlaw.com
jalieberman@pomlaw.com
ahood@pomlaw.com

WOHL & FRUCHTER LLP
Joshua E. Fruchter
(*pro hac vice* application forthcoming)
25 Robert Pitt Drive, Suite 209G
Monsey, New York 10952
Telephone: (845) 290-6818
Facsimile: (718) 504-3773
jfruchter@wohlfruchter.com

Attorneys for Plaintiff